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October 19, 2010



Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e)
Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with Section 8(e): Results of a OECD 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in Wistar Rats with 2-[(2-Heptadec-8-enyl)-4,5-dihydro-imidazol-1-yl]-ethanol (CAS No. 95-38-5)

Dear Sir/Madam:

BASF Corporation is submitting results of a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in Wistar Rats [CrI:WI(HAN)] with 2-[(2-Heptadec-8-enyl)-4,5-dihydro-imidazol-1-yl]-ethanol (CAS No. 95-38-5), conducted by BASF SE, Ludwigshafen, Germany.

The aim of this study was to obtain information on the possible effects of the substance on the integrity and performance of the male and female reproductive systems including gonadal function, mating behavior, conception, gestation and parturition.

The study was carried out with reference to the requirements of the following guidelines:

- OECD Guidelines for Testing of Chemicals; No. 422, Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (22 Mar 1996)
- EPA, Health Effects Test Guidelines; OPPTS 870.3650: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (Jul 2000)

The dose levels were 0; 5, 20 and 100 mg/kg body weight/day (gavage). All animals were observed daily for any clinical signs during the study period. Because of severe clinical findings seen in animals of test group 3 (100 mg/kg bw/d), i.e. respiration sounds, reduced body weights and the death of one female animal on study day 3, the dose level in test group 3 was reduced to 60 mg/kg bw/d for the females on study day 8 as well as for the males on study day 9.

DCN: 88110000024

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After a 14-day pre-mating period, the male and female parental animals were mated overnight in a 1:1 ratio until evidence of copulation (vaginal smear). The day on which sperm was detected was referred to as gestation day (GD) 0 and the following day as GD 1. All surviving parental males were sacrificed and examined after the end of the administration period (at least 28 days). The parental females were allowed to deliver and rear their pups until postnatal day (PND) 4. On PND 4, all pups were sacrificed and examined. Towards the end of the administration period a functional observation battery (FOB) was performed and motor activity was recorded.

The following is a summary of the most relevant results:

Test group 3 (100 mg/kg bw/d between study days 0-7 [females] and 0-8 [males],
60 mg/kg bw/d onwards from study day 8 [females] and 9 [males])

F0 parental animals

- *Clinical Examinations:*
 - One female animal was found dead in study week 1. One male and one female animal were sacrificed moribund state in study week 2.
 - Poor general state in two male and two female animals in study weeks 1 and 2, one male animal in study weeks 3 and 4 and one female animal in study weeks 6 and 7 as well as in one female animal from GD 0 and 1, and up to GD 7 onwards.
 - Reduced nutritional state in one male animal in study week 3, one female animal in study week 1 and two female animals in study weeks 1 and 2 as well as in one female animal from GD 0 to 5.
 - Respiratory sounds in several male and female F0 animals during the entire study period.
 - Piloerection in one female animal in study week 0.
 - Diarrhea in one female animal in study week 2.
 - Significantly decreased food consumption in males during the first two study weeks and in females in the first study week.
 - Significantly decreased male animals' body weight in week 2 and significantly decreased body weight change in week 0-1 and in summary between weeks 0-4.

- *Fertility:*
 - No test-substance related, relevant findings were observed.

- *Clinical Pathology:*
 - No test-substance related, relevant findings were observed.



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- *Pathology:*
 - The male animal which was sacrificed moribund showed severe dilation of the gastro-intestinal tract (stomach, jejunum, colon and cecum) with severe organ size reduction of the thymus.
 - The female animal which was sacrificed moribund showed severe dilation of the gastro-intestinal tract (stomach, jejunum and cecum) with severe organ size reduction of the thymus.

F1 pups

- No test-substance related, relevant findings were observed.

Test group 2: 20 mg/kg bw/d

F0 parental animals

- *Clinical Examinations:*
 - No test-substance related, relevant findings were observed.
- *Fertility:*
 - No test-substance related, relevant findings were observed.
- *Clinical Pathology:*
 - No test-substance related, relevant findings were observed.
- *Pathology:*
 - No test-substance related, relevant findings were observed.

F1 pups

- No test-substance related, relevant findings were observed.

Test group 1: 5 mg/kg bw/d

F0 parental animals

- *Clinical Examinations:*
 - No test-substance related, relevant findings were observed.



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- *Fertility:*
 - No test-substance related, relevant findings were observed.
- *Clinical Pathology:*
 - No test-substance related, relevant findings were observed.
- *Pathology:*
 - No test-substance related, relevant findings were observed.

F1 pups

- No test-substance related, relevant findings were observed.

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

If you have any questions, please call Janet Cerra at (973) 245-6693.

Sincerely,

Janet Cerra

Janet Cerra
Product Regulatory Center of Expertise
North America

/jc

1118th Letter.doc

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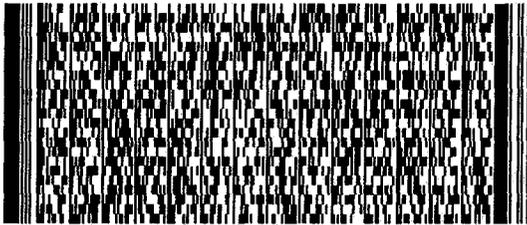
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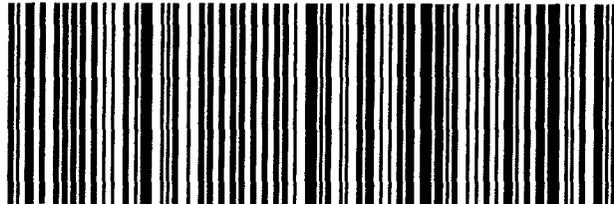
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